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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,723	06/26/2003	Andrew R. Marks	0575/61134-B/IPW/AJM/AJD	6915

30551 7590 12/29/2005

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,723	MARKS, ANDREW R.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/12/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 and 19-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed on 10/12/2005 has been entered. Claims 1, 2, 4, 13, 14, and 16 have been amended. Claims 1-24 are pending. Claims 1-6 and 13-18 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The rejections of claims 1-3 and 13-15 under 35 U.S.C. §112, first paragraph for scope of enablement and written description have been withdrawn in view of amended.

The rejection of claims 2, 4-6, 14, and 16-18 under 35 U.S.C. 112, second paragraph as set forth in the previous Office Action has been withdrawn in view of amended claims.

Claim Rejections under 35 USC § 112, 1st paragraph

The rejection of claims 4, 5, 16, and 17 under 35 U.S.C. §112, first paragraph for scope of enablement, as set forth at pages 3-5 of the previous office action (Paper No. 04192005, mailed on 04/27/2005), is maintained.

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The rejection of claims 4, 5, 16, and 17 under 35 U.S.C. §112, first paragraph for written description, as set forth at pages 5-7 of the previous office action (Paper No. 04192005, mailed on 04/27/2005), is maintained.

Applicants argue that in view of the assays and working examples provided by the specification, one of ordinary skill in the art following the description of the specification would be able to practice the claimed methods without undue experimentation. Specifically, Applicants argue that the skilled artisan could identify 1,4-benzothazepine derivatives which demonstrate efficacy in the claimed methods and working examples would enable a skilled artisan to treat subjects afflicted with atrial tachyarrhythmias and prevent atrial tachyarrhythmias in a subject by administering to the subject an agent which inhibits PKA phosphorylation of RyR2 in the subject's heart, without undue experimentation. This has been fully considered, but is not found to be persuasive because the agents recited in claims 4, 5, 16, and 17 are not limited to 1,4-benzothazepine derivatives. In stead, claims 4, 5, 16, and 17 recite an agent that inhibits dissociation of FKBP12.6 from a type 2 ryanodine receptor. As noted in the previous office action, the specification fails to provide adequate written description for the genus recited in the methods and does not reasonably provide enablement for such a method of employing a genus of agents that inhibits dissociation of a FKBP12.6 from RyR2 receptor.

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Claim Rejections Under 35 U. S. C. § 102 (b)

The rejection of claims 1-6 and 13-18 under 35 U.S.C. 102(b) as being anticipated by Nakaya et al. (British Journal of Pharmacology, 131: 1363-1372, 2000), as evidenced by Yano et al. (*Circulation* 107:477-484, 2003), is maintained.

At the bottom of page 9 of Applicants' response filed on 10/12/2005, Applicants argue that the reference of Nakaya et al. is not a prior art under 35 U.S.C. §102 (b). This is not found be persuasive because the parent applications fail to disclose the instantly claimed method, the claimed subject matter is not entitled to the priority date of parent applications. Thus, the priority date of the instantly claimed invention is 06/26/2003, i. e., the filing date of 10/608,723.

At page 10 of Applicants' response filed on 10/12/2005, Applicants argue that the reference of Nakaya et al. is specifically directed to the effect of JTV-519 on muscarinic acetylcholine receptor-operated K^+ current in isolated guinea-pig atrial cells. In contrast, Applicants' invention is directed to the nicotinic acetylcholine receptor, specifically cAMP dependent protein kinase and tyrosine specific protein kinase. Applicants' argument has been fully considered, but is not deemed to be persuasive because the claims are drawn to a method of treating a subject afflicted with atrial tachyarrhythmia comprising administering to the subject a therapeutically effective amount of an agent that inhibits PKA phosphorylation of RyR2 receptor or dissociation of a FKBP12.6 from RyR2 receptor, whereas Nakaya et al. teach that JTV-519, which is known in the art to inhibit

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PKA phosphorylation of RyR2 receptor and dissociation of FKBP12.6 from the RyR2 receptor, exerts antiarrhythmic effects against atrial fibrillation and may be useful for the treatment of patients with atrial fibrillation. The effect of JTV-519 is inherent to its structure. Since Nakaya et al. teach the same method of treating the same disease comprising administering the same agent to a subject, the teachings of Nakaya et al. meet the limitations of claims 1-6 and 13-18.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
December 23, 2005